CLAIMS

1. Use of an ScFv antibody (ScFv Ab) capable of recognising a disease associated molecule (DAM) in the manufacture of a medicament for the prevention and/or treatment of a disease condition associated with a DAM.

2. Use of an ScFv Ab according to claim 1 wherein the DAM is a tumour associated antigen (TAA).

3. Use according to claim 1 or claim 2 wherein the ScFv Ab has the sequence presented as SEQ ID No 1 or SEQ ID No 2 or a variant, homologue, fragment or derivative thereof.

4. Use according to claim 1 or claim 2 wherein the ScFv Ab has the sequence presented as SEQ ID No 3 or a variant, homologue, fragment or derivative thereof.

5. Use according to claim 1 or claim 2 wherein the ScFv Ab has the sequence presented as SEQ ID No 4 or a variant, homologue, fragment or derivative thereof.

6. A nucleotide sequence encoding the ScFv Ab according to any one of claims 1-5.

7. A nucleotide sequence according to claim 6 wherein the nucleotide sequence has the sequence presented as SEQ ID No 5 or SEQ ID No 6 or a variant, homologue, fragment or derivative thereof.

8. A nucleotide sequence according to claim 6 wherein the nucleotide sequence has the sequence presented as SEQ ID No 7 or a variant, homologue, fragment or derivative thereof.

9. A nucleotide sequence according to claim 6 wherein the nucleotide sequence has the sequence presented as SEQ ID No 8 or a variant, homologue, fragment or derivative thereof.

10. A nucleotide sequence capable of hybridising to the nucleotide sequence according to any

one of claims 6-9 or a sequence that is complementary to the hybridisable nucleotide sequence.

11. A nucleotide sequence according to any one of claims 6-10 wherein the nucleotide sequence is operably linked to a promoter.

12. A construct comprising the nucleotide sequence according to any one of claims 6-11.

13. A vector comprising the nucleotide sequence of any one of claims 6-12.

14. A plasmid comprising the nucleotide sequence of any one of claims 6-13.

15. A host cell comprising the nucleotide sequence of any one of claims 6-14.

16. A process for preparing a ScFv Ab according to any one of claims 1-5 comprising expressing a nucleotide sequence according to any one of claims 6-11 or when present in the expression entity of any one of claims 12-15 and optionally isolating and/or purifying the ScFv Ab.

17. A ScFv Ab produced by the process according to claim 16.

18. An *in vitro* method for obtaining a ScFv Ab according to any of the preceding claims comprising:

(i) preparing a phage library wherein each phage comprises a nucleic acid construct encoding a protein comprising a potential binding domain;

(ii) causing the expression of said potential proteins and the display of the potential binding domains on the outer surface of the phage;

(iii) contacting the phage library with a DAM target under conditions such that the potential binding domains and the DAM target interact;

(iv) separating the phage displaying a domain that binds the DAM target from phage that do not bind;

(v) recovering at least one phage displaying on its outer surface a protein which binds the DAM target;

(vi) amplifying the binding protein *in vitro* to create a second enriched library of binding structures;

(vii) repeating steps (iii) to (vi) at least twice;

(viii) expressing the nucleic acid encoding the binding protein under *in vitro* conditions; and

(ix) determining whether the binding protein interacts with the DAM by detecting the presence or absence of a signal.

19. An *in vitro* method according to claim 18 wherein the *in vitro* method is to screen for a ScFv Ab useful in the treatment of a disease.

20. A process comprising the steps of:

(a) performing the *in vitro* method according to claim 18 or claim 19;

(b) identifying one or more ScFv Abs capable of recognising a DAM by means of a detectable signal; and

(c) preparing a quantity of those one or more ScFv Abs.

21. A process comprising the steps of:

performing the method according to claim 18 or claim 19;

(b) identifying one or more ScFv Abs capable of recognising a DAM by means of a detectable signal; and

(c) preparing a pharmaceutical composition comprising those one or more identified ScFv Abs.

22. A process comprising the steps of:

(a) performing the method according to claim 18 or claim 19;

(b) identifying one or more ScFv Abs capable of recognising a DAM;

(c) modifying those one or more identified ScFv Abs capable of recognising a DAM; and

(d) preparing a pharmaceutical composition comprising those one or more modified ScFv Abs.

23. A ScFv Ab as defined in any one of claims 1 to 5 or according to claim 17 or identified by the *in vitro* method of claim 18 or 19 wherein the ScFv Ab is capable of recognising a TAA.

24. A ScFv Ab according to claim 23 wherein the ScFv Ab is capable of recognising a 5T4 antigen.

25. An antibody having the binding specificity of an scFv according to claim 23 or claim 24 conjugated to any one or more of an isotope, an enzyme, a carrier protein, a cytotoxic drug, a fluorescent molecule and a radioactive nucleotide.

26. A method of affecting a disease *in vivo* with an ScFv Ab; wherein the ScFv Ab recognises a DAM antigen in an *in vitro* method; and wherein the *in vitro* method is the method defined in claim 18 or claim 19.

27. Use of a ScFv Ab or a mimetic thereof as defined in any one of claims 1 to 5 as defined in claim 17 or any one of claims 23 to 25 to prepare a pharmaceutical composition.

28. A pharmaceutical composition as defined in claim 27 comprising a ScFv Ab or a mimetic thereof and another therapeutically useful agent.

29. A pharmaceutical composition according to claim 28 wherein the other therapeutically useful agent is a pro-drug activating enzyme.

30. A pharmaceutical composition according to claim 29 wherein the other therapeutically useful agent is a toxin.

31. A pharmaceutical composition according to claim 27 or claim 28 or claim 29 or claim 30 wherein the ScFv Ab is capable of recognising a 5T4 antigen.

32. Use of a ScFv Ab in the preparation of a pharmaceutical composition according to claims 27-31 for the treatment of a condition associated with a DAM.

33. Use of a ScFv Ab capable of recognising a DAM according to claim 1 in combination with another therapeutically useful agent as defined in claims 28-31 or a nucleotide sequence of interest (NOI) encoding same for the treatment of condition associated with a DAM.

34. Use of a ScFv Ab according to claims 32 or 33 for *in vivo* imaging and/or for adjuvant treatment of a disease associated with a DAM.

35. Use according to claims 32-34 wherein the disease is cancer.

36. Use of an ScFv Ab or mimetic thereof to screen for agents that can modulate the DAM binding specificity of a ScFv Ab wherein the ScFv Ab is an ScFv Ab as defined in claims 1-5 or according to claim 17 or claims 23-25 or is expressed by a nucleotide sequence according to claims 6-12 or a variant, homologue, fragment or derivative thereof.

37. A process for diagnosing a disease condition relating to the expression and/or activity of a DAM in an individual comprising:

(i) providing a nucleotide sequence encoding a ScFv Ab as defined in claims 6-12 or an expression product thereof;

(ii) analysing for the binding of the ScFv Ab to a DAM in a sample derived from the individual;

wherein the binding is indicative of the presence of the DAM in the individual.

38. A method for inducing a therapeutic response in a mammal with a disease condition associated with a DAM *in vivo* which comprises inoculating the mammal with a ScFv Ab or mimetic thereof as defined in claims 1-5 or according to claim 17 or claims 23-25 or a vector to direct expression of a nucleotide sequence according to claims 6-12 or a variant, homologue, fragment or derivative thereof in order to induce a therapeutic response to protect said mammal from the disease condition.

39. A method according to claim 38 wherein the disease condition is a cancer.

40. The use of a ScFv Ab substantially as described herein and with reference to the accompanying Figures.

41. An ScFv for use as a pharmaceutical.

42. An canine 5T4 polypeptide having the amino acid sequence shown in SEQ ID No 14 or a variant, homologue, fragment or derivative thereof.

43. A nucleotide sequence capable of encoding a canine 5T4 polypeptide according to claim 42.

44. A nucleotide sequence according to claim 43, having the sequence shown as SEQ ID NO 15 or a variant, homologue, fragment or derivative thereof.

45. An antibody capable of binding specifically to a canine 5T4 polypeptide according to claim 42.

46. A method of preventing and/or treating a disease associated with a disease associate molecule (DAM), comprising administering an ScFv antibody (ScFv Ab) capable of recognizing a or the DAM.

47. The method of claim 46 wherein the DAM is a tumor associated antigen (TAA).

48. The method according to claim 46 or claim 47 wherein the ScFv Ab has the sequence presented as SEQ ID No 1 or SEQ ID No 2.

49. The method according to claim 46 or claim 47 wherein the ScFv Ab has the sequence presented as SEQ ID No 3.

50. The method according to claim 46 or claim 47 wherein the ScFv Ab has the sequence presented as SEQ ID No 4.

51. A nucleotide sequence encoding the ScFv Ab according claim 46 or claim 47.

52. An isolated nucleic acid molecule encoding an ScFv antibody (ScFv Ab) having a sequence set forth in SEQ ID Nos. 1, 2, 3 or 4 or a variant, homologue, fragment or derivative thereof.

53. The isolated nucleic acid molecule of claim 52 having a sequence set forth in SEQ ID Nos. 1, 2, 3, or 4.

54. An isolated nucleic acid molecule having the nucleotide sequence presented as SEQ ID No 5 or SEQ ID No 6 or a variant, homologue, fragment or derivative thereof.

55. An isolated nucleic acid molecule having the nucleotide sequence presented as SEQ ID

No 7 or a variant, homologue, fragment or derivative thereof.

56. An isolated nucleic acid molecule having the nucleotide sequence presented as SEQ ID No 8 or a variant, homologue, fragment or derivative thereof.

57. An isolated nucleic acid molecule having the nucleotide sequence presented as SEQ ID No 5 or SEQ ID No 6.

58. An isolated nucleic acid molecule having the nucleotide sequence presented as SEQ ID No 7.

59. An isolated nucleic acid molecule having the nucleotide sequence presented as SEQ ID No 8.

60. A nucleotide sequence capable of hybridising to the nucleotide sequence according to any one of claims 54-59 or a sequence that is complementary to the hybridisable nucleotide sequence.

61. A nucleotide sequence according to any one of claims 54-59 wherein the nucleotide sequence is operably linked to a promoter.

62. A nucleotide sequence according to claim 60 wherein the nucleotide sequence is operably linked to a promoter.

63. A construct, vector, plasmid host cell comprising the nucleotide sequence according to any one of claims 54-59.

64. A construct, vector, plasmid host cell comprising the nucleotide sequence according to claim 60.

65. A construct, vector, plasmid host cell comprising the nucleotide sequence according to claim 61.

66. A process for preparing an ScFv antibody (ScFv Ab) capable of recognizing a disease associated molecule comprising expressing a nucleic acid molecule of any one of claims 54-59 and optionally isolating and/or purifying the ScFv Ab.

67. A process for preparing an ScFv antibody (ScFv Ab) wherein DAM is TAA.

68. A process for preparing an ScFv antibody (ScFv An) wherein ScFv Ab has a sequence as presented in SEQ ID Nos 1, 2, 3, or 4.

69. A ScFv Ab produced by the process according to claim 66.

70. An *in vitro* method for obtaining a ScFv Ab according to claim 69 comprising:

(i) preparing a phage library wherein each phage comprises a nucleic acid construct encoding a protein comprising a potential binding domain;

(ii) causing the expression of said potential proteins and the display of the potential binding domains on the outer surface of the phage;

(v) contacting the phage library with a DAM target under conditions such that the potential binding domains and the DAM target interact;

(vi) separating the phage displaying a domain that binds the DAM target from phage that do not bind;

(v) recovering at least one phage displaying on its outer surface a protein which binds the DAM target;

(vi) amplifying the binding protein *in vitro* to create a second enriched library of binding structures;

(vii) repeating steps (iii) to (vi) at least twice;

(viii) expressing the nucleic acid encoding the binding protein under *in vitro* conditions; and

(ix) determining whether the binding protein interacts with the DAM by detecting the presence or absence of a signal.

71. An *in vitro* method according to claim 70 wherein the *in vitro* method is to screen for a ScFv Ab useful in the treatment of a disease.

72. A process comprising the steps of:

(a) performing the *in vitro* method according to claim 70 or claim 71;

(b) identifying one or more ScFv Abs capable of recognising a DAM by means of a detectable signal; and

(c) preparing a quantity of those one or more ScFv Abs.

73. A process comprising the steps of:

performing the method according to claim 70 or claim 71;

(b) identifying one or more ScFv Abs capable of recognising a DAM by means of a detectable signal; and

(c) preparing a pharmaceutical composition comprising those one or more identified ScFv Abs.

74. A process comprising the steps of:

(a) performing the method according to claim 70 or claim 71;

(b) identifying one or more ScFv Abs capable of recognising a DAM;

(c) modifying those one or more identified ScFv Abs capable of recognising a DAM; and

(d) preparing a pharmaceutical composition comprising those one or more modified ScFv Abs.

75. A ScFv antibody (ScFv Ab) cabaple of recognizing a TAA identified by the method of claim 70 or claim 71.

76. A ScFv Ab according to claim 75 wherein the ScFv Ab is capable of recognising a 5T4 antigen.

77. An antibody having the binding specificity of an scFv according to claim 75 conjugated to any one or more of an isotope, an enzyme, a carrier protein, a cytotoxic drug, a fluorescent molecule and a radioactive nucleotide.

78. A method of affecting a disease *in vivo* with an ScFv Ab; wherein the ScFv Ab recognises a DAM antigen in an *in vitro* method; and wherein the *in vitro* method is the method defined in claim 70 or claim 71

79. A pharmaceutical composition comprising the ScFv Ab of claim 69.

80. The pharmaceutical composition of claim 79 further comprising another therapeutic agent.

81. The pharmaceutical composition of claim 80 wherein the other therapeutically useful agent is a pro-drug activating enzyme.

82. The pharmaceutical composition of claim 81 wherein the other therapeutically useful agent is a toxin.

83. A pharmaceutical composition according to claim 79 or claim 80 or claim 81 or claim 82 wherein the ScFv Ab is capable of recognising a 5T4 antigen.

84. The method of claim 46 further comprising administering a pro-drug activating enzyme or toxin.

85. A method for *in vivo* imaging and/or adjuvant treatment of a disease associated with a disease associated molecule (DAM) comprising administering an ScFv antibody (ScFv Ab).

86. The method according to claim 85 wherein the disease is cancer.

87. A method for screening for agents that modulate a disease associated molecule (DAM) by contacting a DAM with an ScFv Ab as claimed in 69.

88. A process for diagnosing a disease condition relating to the expression and/or activity of adisease associated molecule (DAM) in an individual comprising:

(i) providing a nucleotide sequence encoding a ScFv Ab as defined in claims 52-56 or an expression product thereof;

(ii) analysing for the binding of the ScFv Ab to a DAM in a sample derived from the individual;

wherein the binding is indicative of the presence of the DAM in the individual.

89. A method for inducing a therapeutic response in a mammal with a disease condition associated with a disease associated molecule (DAM) *in vivo* which comprises inoculating the mammal with a ScFv Ab as claimed in claim 69.

90. A method according to claim 89 wherein the disease condition is a cancer.

91. A pharmaceutical comprising an ScFv.

92. An isolated canine 5T4 polypeptide having the amino acid sequence shown in SEQ ID No 14.

93. An isolated nucleotide sequence capable of encoding a canine 5T4 polypeptide according to claim 92.

94. An isolated nucleotide sequence according to claim 43, having the sequence shown as SEQ ID NO 15.

95. An isolated antibody capable of binding specifically to a canine 5T4 polypeptide according to claim 92.